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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,143	07/25/2003	Mark S. Spector	N.C. 84,766	3910
26384 7590 05/18/2007 NAVAL RESEARCH LABORATORY ASSOCIATE COUNSEL (PATENTS) CODE 1008.2 4555 OVERLOOK AVENUE, S.W. WASHINGTON, DC 20375-5320				
			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/627,143

Applicant(s)

SPECTOR ET AL.

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 30, 31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

The remarks and amendment filed 2/6/07 are acknowledged.

#### *Election/Restrictions*

Applicant's election of Group II, claims 27-33, the hydrogel specie of claim 18 and a protein as the analyte in the reply filed on 4/20/06 is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that claim 27 has been amended to include the composition limitations of claims 1, 18 and 19. However, the examination remains limited to the specie originating from claim 18.

Claims 1-26, 28, and 29 stand withdrawn from further consideration.

Claims 27 and 30-33 remain under examination.

#### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27, 30, 31 and 33 stand rejected under 35 U.S.C. 102(e) as being anticipated by Boschetti et al. (US 2003/0218130; referred to as "Boschetti").

Applicant argues that Boschetti involves the use of a non-ionic polysaccharide while the instant application involves the use of a regioregular polyacrylate poly(6-acryloyl-beta-O-methyl galactopyranoside) which is allegedly "separate and distinct from a Polysaccharide." Applicants submit that polysaccharides have a composition and chemical structure that is very different from

Art Unit: 1651

this polyacrylate and recite properties related to pore diameter and IPN architecture and gel mechanical integrity. Applicants conclude that Boschetti does not involve a poly(6-acryloyl-beta-O-methyl monosaccharide) structure as a base material, wherein this material has such large pores and a mechanically strong IPN structure that would not have been obvious to one of skill in the art.

Applicant's arguments filed 2/6/07 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a poly(6-acryloyl-beta-O-methyl monosaccharide) structure as a base material, wherein this material has such large pores and a mechanically strong IPN structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are directed to a method for assaying biomolecules comprising functionalizing a support with acrylate groups and reacting said acrylate groups with a hydrogel polymer containing a sugar (emphasis added) which is the polymerization product reaction product of a sugar compound with a polymerizable double bond, a cross-linker with two or more double bonds and a third compound that is 2-acylamidohydroxyacetic acid (the elected specie). As previously discussed in the first Office action:

"Boschetti discloses several reaction pathways to achieve the immobilized, derivatized hydrogels. The anchor reagent is bound to the substrate surface. The anchor reagent can be methacryloyloxypropyltrimethoxy silane or glycidyl methacrylate (p. 15-16, bridging paragraph and Fig. 5), both of which meet the limitation of an acrylate functionalized support, as in instant claim 27A. In one embodiment, a modified polysaccharide (emphasis added) having a first polymerizable moiety and a polymerization initiator are contacted with the substrate surface comprising the bound anchor reagent having a second polymerizable moiety (the acrylate). Co-polymerization takes

place to yield a hydrogel comprising a derivatized polysaccharide that is grafted to the surface of a device via links resulting from the polymerization reaction (section 0104), as in instant claim 27B. Boschetti discloses that the modified polysaccharide used in the polymerization reaction can be cross-linked by typical cross-linkers such as bisacrylamide or those disclosed in section 0019 to couple the polymerizable moieties on the polysaccharides (sections 0105). Bisacrylamide has two double bonds and meets the structural limitation for the cross-linkers recited in instant claim 1. Binding functionalities can be provided before polymerization of the derivatized, cross-linked polysaccharide to the device surface having the second polymerizable moiety (section 0107).

The disclosure of a derivatized polysaccharide is a dextran that is derivatized with polymerizable group including allyl, acroyl, methacroyl and vinyl (section 0074-0075), meets the structural requirements of the sugar compound recited in instant claim 1. The disclosed hydrogel can comprise binding functionalities such as sulfonate, phosphate, amino, thiol or carboxyl, for example. A carboxyl binding group is achieved by incorporating 2-acrylamidoglycolic acid or derivatives thereof (section 0082). This disclosure meets the elected specie of instant claim 18, a 2-acrylamidohydroxyacetic acid, because 2-acrylamidoglycolic acid is a synonym for 2-acrylamidohydroxyacetic. The disclosure of 2-acrylamidoglycolic acid meets the limitations regarding the third compound listed in instant claim 1 because it comprises a polymerizable double bond ("acryl") and a carboxyl group.

The immobilized hydrogel comprising dextran having a double bond, a cross-linker with two double bonds and a binding functionality this is a carboxyl group via the elected third compound recited in instant claim 18, is then reacted with a biomolecule such as a polypeptide, protein, carbohydrate, lipid or nucleic acid which can be used to bind receptors, antibodies, small organic compounds, etc. (section 0123 and claim 67 of the referenced patent). This disclosure meets part D. of instant claim 27. The disclosure of a protein as the attached biomolecule satisfies instant claim 30. The biomolecule can be labeled with a fluorophore, as in instant claim 31 (assuming that "fluorophrone" is "fluorophore"). An example is FITC-labeled Concanavalin A (section 0181). Boschetti teaches that the assays using the disclosed immobilized hydrogels can be detected by fluorescence, UV, visible, immuno methods, for example (sections 0137-0140), as in instant claim 33 (assuming that instant claim 33 was intended to depend from instant claim 27). Boschetti discloses

Art Unit: 1651

that the functionalized hydrogel was used to assay for glucosides and mannosides (section 0192-0193), thus meeting the assay step in instant claim 27D."

A "sugar" is a generic term for any type of saccharide. A polysaccharide meets the limitation of a sugar. Neither the claims nor the specification specifically limit the meaning of a sugar to a monosaccharide.

No claim is allowed.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

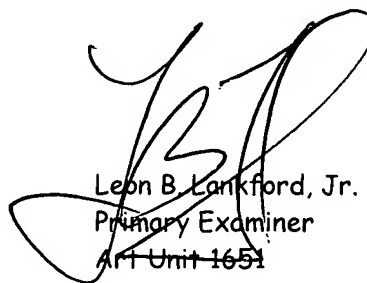
Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley  
Patent Examiner  
1651



Leon B. Lankford, Jr.  
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Art Unit 1651